K070702

SUMMARY OF SAFETY AND EFFECTIVENESS DATA

Dr. Jan G. Stannard
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DEVICE
Trade Name: *Fusion Core Material*
Classification Name: Cement, Dental
FDA Product Code: 872.3275

MAY 10 2007

PREDICATE DEVICES:
Clearfil Photo Core, Kuraray
SuperCure, Centrix
Rebilda LC #, Voco
EnCore, Centrix

DESCRIPTION AND INTENDED USE:
Fusion Core is a high strength core material that offers the convenience of light curing with excellent depth of cure that allows either the layering or the core form approach to build-up. Fusion Core cuts just like dentin without clogging the cutting bur as many other BIS-GMA containing materials. Fusion Core contains no BIS-GMA and is based upon a hydrophilic resin/filler combination

COMPARISON WITH PREDICATE PRODUCTS:
Fusion Core Material is substantially equivalent in design, composition and intended use to the products listed above.

SAFETY AND EFFECTIVENESS:
The Fusion Core Material is substantially equivalent in design, composition, performance, intended use and effectiveness to the predicate kit products listed above.

The predicate products have been found substantially equivalent under the 510(k) premarket notification process as Class II Dental Devices under CFR EBC 872.3765.

According to the NIH Technology Assessment conference on *Effects and Side-Effects of Dental Restorative Materials:* "General usage of these materials over about 30 years indicates a high benetif-to-risk ratio...both composites and glass ionomers are relatively trouble-free. There is no evidence of short-term or long-term risk...There is no suspicion of any problems after virtually billions of procedures in the United States.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Dr. Jan G. Stannard
President
Denali Corporation
134 Old Washington Street
Hanover, Massachusetts 02339-1629

MAY 10 2007

Re: K070702
Trade/Device Name: Fusion Core Material
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: II
Product Code: EBF
Dated: April 23, 2007
Received: April 25, 2007

Dear Dr. Stannard:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Chiu S. Lin, PhD
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510 (k) Number K070702
(if known)

Device Name

Fusion Core Material

Indications for Use:

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner
(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices
510(k) Number K070702

Prescription Use ✓ *or* *Over-The-Counter Use*
(Per 21 CFR 801.109)